Summary
21 CFR Part 807.92

K# K012387

Date: January 22, 2002

Contact:

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Submission Correspondent:

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Device Name: STG Monitor Multichannel Lung Sound Analysis System

Common Name: Pulmonary Function Interpretator

Classification: The classification name, 21 CFR Part and Paragraph Number, product code, classification and tier categorization follows:

Classification Name	21 CFR Section	Product Code	Class	Tier
Calculator, Pulmonary Function Interpretation calculator	868.1900	BZM	II	2

Predicate Devices: The Stethographic STG Monitor Multichannel Lung Sound Analysis System is substantially equivalent to the following released to market device:

Device	Manufacturer	510(k) #
Pulmotrack, Model 1010	Karmel Medical Acoustic Technologies, Ltd.	K980978

Device Description: The Stethographic STG Monitor Multichannel Lung Sound Analysis System Comprises Chest pad with electronic

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Device	Manufacturer	510(k) #
Pulmotrack, Model 1010	Karmel Medical Acoustic Technologies, Ltd.	K980978

Device Description: The Stethographic STG Monitor Multichannel Lung Sound Analysis System Comprises Chest pad with electronic

	stethoscopes, back pad, pre-amplifier, connection hub, and a PC computer. The system also includes a printer, a cart, speakers, headphones, re-writable CDs for data storage and custom software. The system is non-invasive with patient contact disposable cotton cover.
Indications:	The Stethographics STG Multichannel Lung sound Analysis system is intended for the recording, audio reproduction, graphic display and automated identification of lung sounds. It can be configured to record from one or more than one channels.
Technological Characteristics:	The Stethographic STG Monitor Multichannel Lung Sound System Analysis device is virtually the same as the Pulmotrack, Model 1010.
Performance:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Stethographic STG Monitor Multichannel Lung Sound Analysis System is same as the predicate device.
Conclusions	In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in the premarket notification, Stethographics, Inc., concludes that the Stethographic STG Monitor Multichannel Lung Sound Analysis System is safe and effective and substantially equivalent to the predicate devices as described herein.
Other:	Stethographics, Inc., will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2002

Mr. Harvey Knauss
Stethographics, Inc.
c/o Delphi Consulting Group
11874 S. Evelyn Circle
Houston, TX 77071

Re: K012387
STG Monitor Multichannel Lung Sound Analysis System
Regulation Number: 868.1900
Regulation Name: Diagnostic Pulmonary-Function Interpretation Calculator
Regulatory Class: II (two)
Product Code: BZM
Dated: December 20, 2001
Received: January 24, 2002

Dear Mr. Knauss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K012387

Device Name: STG Monitor Multichannel Lung Sound Analysis System.

Indications for use: The Stethographics STG Multichannel Lung Sound Analysis system is intended for the recording, audio reproduction, graphic display and automated identification of lung sounds. It can be configured to record from one or more than one channel.

Prescription Device.

Federal Law (US) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012387

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)